HSR INTERNET UPDATES

https://www.epa.gov/osa/basic-information-about-human-subjects-research-0

Add a new first tab on the right-hand side of the site that reads: *Program in Human Research Ethics and Oversight (PHREO) Overview.* Place it above the "What is human subjects research" tab so that it is the first page a viewer sees when clicking on the main link above. Text for first tab:

> OSA's Program in Human Research Ethics and Oversight (PHREO) supports the ethical conduct and regulatory compliance of human subjects research conducted or supported by the EPA. This support is accomplished through project review, cross-agency partnership, and education and training. The PHREO reviews, supports, and guides the work of EPA affiliated or supported researchers involved in human subjects research to ensure that the rights and welfare of human research subjects are protected. The PHREO is in place to ensure that all EPA employees, contractors, grant recipients, and parties to other EPA agreements adhere to the highest standards of ethical conduct and are properly informed of the regulatory aspects of research involving human subjects. All research involving human subjects proposed by EPA staff or EPA supported researchers must be approved by the EPA Human Subjects Research Review Official (HSRRO) before human subjects work may begin.
>
> Human subjects research (HSR) at the Environmental Protection Agency (EPA) allows for the collection of valuable information necessary for characterizing and controlling risks to public health. Research involving human subjects informs decision-making and the formulation of regulatory standards at the Agency. HSR is critical for EPA's program offices to consider when making regulatory decisions under many of the programs it administers, e.g., National Ambient Air Quality Standards, water quality criteria and drinking water standards, pollution mitigation techniques, and pesticide registration. HSR studies advance scientists' understanding of the links between human health and the environment so that the EPA is better able to carry out its mission.

Additional edits to other tabs below:

4th tab down: "How does EPA protect human subjects?"

- **Delete current second paragraph and insert the following updated language:** All human subjects research is evaluated by an administrative body, known as an Institutional Review Board (IRB), which is designated with protecting the rights and welfare of human research subjects in research activities. IRB authority is codified at 40 CFR 26. The IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities that fall within its jurisdiction.

- **Delete current third paragraph and insert the following updated language:** EPA holds a Federal-Wide Assurance (FWA), which is an assurance of compliance that covers

the engagement of the Agency in any Human Subjects Research conducted or supported by any Common Rule agency, including EPA. This assurance covers all Agency components and therefore provides a basis for the participation of EPA personnel anywhere in the Agency in HSR under conditions that are compliant with applicable regulations.

- **Delete current fourth paragraph and insert the following updated language:** EPA Order 1000.17 A (Policy and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research) establishes EPA procedures and responsibilities for implementing the requirements set forth in 40 CFR Part 26. The Order requires that all human subjects research conducted or supported by EPA must either be approved or be acknowledged as exempt research by the EPA Human Subjects Research Review Official (HSRRO) before any work involving human subjects research can begin. Preliminary (or "conditional") review by the HSRRO is not required, but can be requested, for any research project, contract, grant application, cooperative agreement, cooperative research and development agreement (CRADA), interagency agreement or any formal agreement involving EPA support of such studies. The Order describes the requirements for review, as well as the responsibilities of all parties involved in EPA research in protecting the rights and welfare of human research subjects.

- **Delete current fifth paragraph and insert the following updated language:** EPA's National Exposure Research Laboratory (NERL) published SEAOES as a resource document for researchers to consult as they develop and conduct observational human exposure studies. EPA Order 1000.17 A requires that all human observational exposure studies conducted or supported by EPA adhere to the principles set forth in SEAOES. SEAOES provides information on regulatory requirements, sound scientific practices, and ethical issues to consider when performing observational human exposure studies.

7th tab down: "What is required for HSRRO approval?"

- **Fifth paragraph (edits):** In addition to complying with the applicable regulations, EPA conducted or supported studies must also comply with EPA Oder 1000.17A, *Policy and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research.* This document was updated in 2016 to ensure that it is consistent with contemporary research practice and applicable regulations. ~~Although EPA has, in the past, interpreted the Policy Order as broadening the types of studies that could be considered intentional exposure research, the Agency is currently revising the Policy Order to include the regulatory definition of intentional exposure research and to otherwise ensure consistency with the applicable regulations. In the meantime, as indicated herein, the Agency has revised its interpretation of the current Policy Order to be consistent with its regulations.~~

- **Sixth/Seventh paragraph (suggested edits):** To obtain approval or a concurrence of exemption by the HSRRO, researchers must submit the IRB-approved research package or documentation of exemption, including evidence of IRB approval and any correspondence between the IRB and the researchers.

  ~~Required documentation for HSRRO review varies by project type, but typically-required documentation is outlined below.~~

  ~~Documentation must typically include:~~

- ~~Full research plan~~
- ~~Current IRB documentation including:~~
  - ~~IRB application~~
  - ~~Approval Letter~~
  - ~~Consent documents~~
  - ~~Recruitment materials~~
  - ~~Surveys, questionnaires, interview scripts, etc.~~
- ~~If applicable, submission must also include grant or fellowship documentation, master protocols and documentation of ethics training.~~